

**Fast Track Drug Development Programs: Designation and Review Programs**  
**SOPP 8414**  
**Appendix 3**  
**Submission of Portion of Application (SOPA) Accepted Letter**

---

Our Reference: BB-IND [ XXXX/XXX ]

[ SPONSOR'S NAME ]  
[ INSTITUTION'S NAME ]  
[ ADDRESS ]

Dear [ SPONSOR'S NAME: ]

Reference is made to your request of [ DATE ], for review of your planned Biologics License Application (BLA) under provision (c) of Section 506 of the Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 356) for your Fast Track product, [ PRODUCT NAME ] for [ APPROVED FAST TRACK DEVELOPMENT PROGRAM ]. This provision provides that the Agency shall evaluate for filing, and may commence review of portions of, an application for the approval of a product before the sponsor submits a complete application provided that the applicant provides a schedule for submission of information necessary to make the application complete and pays any fee that may be required under Section 736. This evaluation is predicated upon a determination by the Agency, after preliminary evaluation of clinical data submitted by the sponsor, that the product may be effective. The Agency has determined, following this preliminary evaluation, that this requirement has been met by the clinical data as reviewed to date.

We have reviewed your [ DATE ] submission to your IND which outlines the proposed schedule of your submission of each portion of your BLA as required by law. We have reviewed your proposed schedule and find it acceptable.

If you any have questions, please contact [ RPM NAME ], Division of [ DIVISION NAME ], at (301) 827-[ XXXX ].

Sincerely yours,

[ DIRECTOR'S NAME ]  
Director  
Division of [ XXXXX ]  
Office of [ XXXX ]  
Research and Review  
Center for Biologics  
Evaluation and Research

Application Number [BLA/IND/NDA/510(k)/PMA] \_\_\_\_\_

Letter Type: SOPA ACCEPTED (RB)

Cc: Clinical Trial Branch Chief  
Clinical Trial Branch/Division Special Assistant  
HFM-110/RIMS  
HFM-4/QAS  
Office Director  
HFM-500/B. Goldman  
Review Committee  
Division Regulatory Project Manager  
All Office Division Directors

History

File Name

Concurrence box

Office	Name/Signature	Date